



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

May 20, 2003

WARNING LETTER
CHI-14-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Meryl J. Squires, President
Merix Pharmaceutical Corporation
18 Dundee Road, Bldg. 3
Suite 204
Barrington, IL 60010

Dear Ms. Squires:

This letter is in reference to your firm's marketing and distribution of ViraMedx® with Viracea®, ViraMedx® with Viracea® Shingle-EEZE Topical Anti-Viral Spray, and ViraMedx RELEEV™. The labeling for these products states that they contain Viracea, in addition to other ingredients. During the inspection of your firm, our investigators were told that Viracea is a combination of benzalkonium chloride and echinacea (also identified as *Echinacea purpurea*). Statements on the immediate containers and/or cartons for these products include claims that cause them to be drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Additionally, promotional literature that you distribute in connection with your products as well as the information on two of your Internet web sites: www.viramedx.com and www.herpesccontrol.com, bear claims such as those listed below that cause the products to be drugs.

ViraMedx® with Viracea®:

"The Solution x Cold Sores x Fever Blisters x Other Herpes Related Outbreaks"
"***ViraMedx® "kills" the herpes virus in cultured human cells. It stops the virus that causes cold sores!" (carton)

Other promotional claims on both Internet web sites include the following:

"ViraMedx® demonstrates antiviral activity so that it actually inactivates the herpes virus."

"***ViraMedx® is antiviral to the herpes virus and is effective on acyclovir resistant strains of herpes."

"Viracea is a new antiviral treatment of the herpes family of viruses: Herpes Simplex Virus 1 (HSV1), Herpes Simplex Virus 2 (HSV2), Varicella Zoster Virus (VZV) or shingles, and cytomegalovirus. In laboratory testing Viracea 2,4 has demonstrated Anti-Viral™ activity and effectiveness against the HIV virus. Potential uses and markets for Viracea as a new Anti-Viral™ are:

Topical treatment of cold sores / fever blisters, Genital herpes, Herpes keratitis, Herpes conjunctivitis, Oral gingival stomatitis, Shingles, Human papillomavirus (warts) *. Based on the laboratory results of the Viracea 2,4 formula, potential additional uses and markets are: Systemic treatment of HIV, Hepatitis C, Mononucleosis, Cytomegalovirus."**

"Viracea has demonstrated effectiveness on: oral labial tissue, herpetic gingivostomatitis, herpes genitalis, herpes keratitis, and herpetic whitlow."

ViraMedx® with Viracea® Shingle-EEZE Topical Anti-Viral Spray:

**" Even better when used with ViraMedx® with Viracea® Internal Anti-Viral Support."
(immediate container)**

"Viracea is a new antiviral treatment of the herpes family of viruses: Herpes Simplex Virus 1 (HSV1), Herpes Simplex Virus 2 (HSV2), Varicella Zoster Virus (VZV) or shingles, and cytomegalovirus. In laboratory testing Viracea 2,4 has demonstrated Anti-Viral™ activity and effectiveness against the HIV virus. Potential uses and markets for Viracea as a new Anti-Viral™ are:

Topical treatment of cold sores / fever blisters, Genital herpes, Herpes keratitis, Herpes conjunctivitis, Oral gingival stomatitis, Shingles, Human papillomavirus (warts) *. Based on the laboratory results of the Viracea 2,4 formula, potential additional uses and markets are: Systemic treatment of HIV, Hepatitis C, Mononucleosis, Cytomegalovirus."**

"Viracea has demonstrated effectiveness on: oral labial tissue, herpetic gingivostomatitis, herpes genitalis, herpes keratitis, and herpetic whitlow."

Other promotional claims for this product on both Internet web sites include the following:

"Shingle-EEZE™ is the topical spray formulation for use in treating shingles. Caused by the varicella zoster virus (VZV), there is currently nothing on the market that directly treats this very painful disease effectively until now...May decrease mortality rate of sufferers...Viracea has demonstrated effectiveness on: oral labial tissue, herpetic gingivostomatitis, herpes genitalis, herpes keratitis, and herpetic whitlow."

ViraMedx RELEEV™:

“Published laboratory testing at The [sic] leading [REDACTED] proves RELEEV™ ‘kills’ the herpes virus, both HSV1 & HSV2, in cultured human cells. It stops the virus that causes cold sores.” (carton)

Other promotional claims on both Internet web sites include the following:

“ViraMedx Releev™ is an over-the-counter topical formulation of Viracea targeting the herpes virus. . . . resolved herpes virus outbreaks . . . When ViraMedx Releev™ was applied at the initial prodromal period, the outbreak and [sic] never occurred . . . is marketed for the topical treatment of infectious skin lesions caused by the herpes virus. . . . primarily for cold sores, oral gingival stomatitis, herpes genitalis, shingles and chicken pox.”

“ViraMedx Releev™ demonstrates antiviral activity so that it actually inactivates the herpes virus consistently relieved all pain associated with herpes outbreaks in minutes . . . is antiviral to the herpes virus and is effective on acyclovir resistant strains of herpes Newborns have died recently due to acyclovir resistant strains of herpes.

“Viracea is a new antiviral treatment of the herpes family of viruses: Herpes Simplex Virus 1 (HSV1), Herpes Simplex Virus 2 (HSV2), Varicella Zoster Virus (VZV) or shingles, and cytomegalovirus. In laboratory testing Viracea 2,4 has demonstrated Anti-Viral™ activity and effectiveness against the HIV virus. Potential uses and markets for Viracea as a new Anti-Viral™ are:

Topical treatment of cold sores / fever blisters, Genital herpes, Herpes keratitis, Herpes conjunctivitis, Oral gingival stomatitis, Shingles, Human papillomavirus (warts) ***. Based on the laboratory results of the Viracea 2,4 formula, potential additional uses and markets are: Systemic treatment of HIV, Hepatitis C, Mononucleosis, Cytomegalovirus.”

“Viracea has demonstrated effectiveness on: oral labial tissue, herpetic gingivostomatitis, herpes genitalis, herpes keratitis, and herpetic whitlow.”

Based on the intended uses cited above, these products are drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). As drugs, the labeling claims made for these products subject them to the requirements for new drugs [Section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their claimed uses. A new drug may not be legally marketed in the U.S. without prior approval from FDA as described in Section 505(a) of the Act [21 USC 355(a)].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [Section 502(f)(1) of the Act].

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The above-listed violations are not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct and prevent the recurrence of these objectionable conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to George F. Bailey, Compliance officer, at the address listed above.

Sincerely,

/s/
Arlyn H. Baumgarten
District Director

cc:

